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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/942,055   | 08/29/2001  | Robert Powers        | GI-5452 C1          | 8112             |
| 25291  | 7590        | 10/02/2003           | EXAMINER            |                  |
| WYETH<br>PATENT LAW GROUP<br>FIVE GIRALDA FARMS<br>MADISON, NJ 07940 |             |                      | MAHATAN, CHANNING   |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1631                |                  |

DATE MAILED: 10/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                 |                               |  |
|------------------------------|---------------------------------|-------------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>09/942,055   | Applicant(s)<br>POWERS ET AL. |  |
|                              | Examiner<br>Channing S. Mahatan | Art Unit<br>1631              |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-44 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **Restriction/Election Requirement**

#### *CLAIM RENUMBERING*

The numbering of claims is not in accordance with 37 C.F.R. § 1.126 which requires the numbering of the original claims to be consecutive. Absent from the original claim numbering was a claim 29. To further prosecution original claims 30-45 have been renumbered as 29-44, respectively. Therefore, pending claims 1-44 are subject to the below restriction/election practice.

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 1-9; drawn to a representation of the three-dimensional structure of an RGS protein or portion, classified in class 702, subclasses 19 and 27.
- II. Claims 10-16, 18, 19-24, 26-28, 29, 31-37; drawn to a method for identifying a modulator of RGS activity, binding or RGS-Gα complex activity, classified in class 435, subclass 4.
- III. Claims 17, 25, 30, and 38; drawn to a modulator, classified in class 530, subclasses 300 and 350.
- IV. Claims 39-43, drawn to a method for identifying a mutant of RGS4, classified in class 530, subclass 300 and 350.
- V. Claim 44, drawn to a method for identifying potential modulators of an RGS protein, classified in class 702, subclass 19 and 22.

The inventions are distinct, each from the other because:

The inventions of Groups (II, IV, and V) and Group I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be

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shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the representation of the three-dimensional structure of an RGS protein or portion of Group I can be used in the alternative inventions of Group II (method for identifying a modulator of RGS activity, binding or RGS-G $\alpha$  complex activity), IV (method for identifying a mutant of RGS4), and V (method for identifying potential modulators of an RGS protein).

The inventions of Groups (II and V) and Group III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case the inventions of Groups II (method for identifying a modulator of RGS activity, binding or RGS-G $\alpha$  complex activity) and V (method for identifying potential modulators of an RGS protein) all indicate the production of a modulator (Group III).

The inventions of Groups I and III are independent inventions because they are directed to different chemical types regarding the critical limitations therein. For Group I the critical feature is a representation of the three-dimensional structure (i.e. data) and for Group III the critical feature is a modulator (i.e. peptide). It is pointed out that processing that may connect two Groups does not prevent them from being viewed as distinct because enough processing can result in producing any composition from any other composition if the processing is not limited as to additions, subtractions, enzyme action, etc. Thus, the two Groupings I and III are independent and/or distinct invention types for restriction purposes.

The inventions Groups III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04, M.P.E.P. § 808.01). In the instant case the different inventions directed to products and methods having different functions, different effects, and different modes of operations. Group III is a modulator (product), whereas Group IV is a method for identifying a mutant of RGS4. Further, the method of Group IV does not involve the use or identification of a modulator (Group III) nor is a modulator recited as being a mutant of RGS4. Thus, Group I and II have different functions, different effects, and different modes of operation.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

*INVENTORSHIP AMENDMENT*

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

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*EXAMINER INFORMATION*

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: *September 28, 2003*  
Examiner Initials: *CSM*

*Marianne P. Allen*  
MARIANNE P. ALLEN  
PATENT EXAMINER  
GROUP 1800  
*Art 1631*